requesting certification. A copy of the label or labeling to be used for the batch must accompany the sample. Under § 80.39, the person to whom a certificate is issued must keep complete records showing the disposal of all the color additive covered by the certificate. Such records are to be made available upon request to any accredited representative of FDA until at least 2 years after disposal of all of the color additive.

The request for certification of a batch of color additive is reviewed by FDA's Office of Cosmetics and Colors to verify that all of the required information has been included. Since the information required in the request for certification is unique to the specific batch of color additive involved, it must be generated for each batch. The information submitted with the request helps FDA to ensure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States. The batch number assigned by the manufacturer is a means of temporary identification until a certification lot number has been issued by FDA. After certification, the manufacturer's batch number helps assure that the proper batch of color is indeed being used under the certification lot number issued by FDA. In the case of a batch that has been refused certification for noncompliance with the regulations, the manufacturer's batch number aids in tracing the ultimate disposition of that batch of color additive. The batch weight serves to account for the disposition of the entire batch; for example, it might be used in determining whether uncertified color has been sold under the lot number assigned to the batch by FDA or, in the event of a recall after certification, to determine whether all unused color has been recalled. In addition, the batch weight is the basis for assessing the certification fee. The name and address of the manufacturer of the color additive being submitted for certification allows FDA to contact the person responsible for its manufacture should a question arise concerning compliance with the regulations. Information on storage conditions pending certification is used to evaluate the possibility that the batch could have been inadvertently or intentionally altered in a manner that would make the sample submitted for certification analysis no longer representative of the batch. It is also used when an FDA investigator is sent to the site; the veracity of the storage statements is checked during normal plant inspections. Information on the uses which the person seeking certification proposes that the color be certified for it is to assure that all of the proposed uses are within the limits of the listing regulation. The statement of the fee on the certification request is for accounting purposes so that the person seeking certification can be promptly notified if any discrepancies appear. The information requested on the label of the sample submitted with the certification request is to identify the sample. The regulations require an accompanying copy of the label or labeling to be used for the batch so that FDA can verify that the batch will be labeled appropriately when it enters commerce.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
80.21	20	152	4,091	0.2	818
80.22	20	152	4,091	0.05	205
Total					1,023

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
80.39	27	152	4,091	.25	1,023
Total					1,023

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated total annual burden for this information collection is 2,046 hours. Over the period fiscal year (FY) 1995 to FY 1997, FDA processed an average of 4,091 requests for certification of batches of color additive. Approximately 20 different respondents submitted requests for certification each year over the period FY 1995 to FY 1997. The estimates for the length of time necessary to prepare certification requests and accompanying samples, and to comply with recordkeeping requirements, were obtained from industry program area personnel.

Dated: May 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13228 Filed 5–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Open Meeting for Representatives of Health Professional Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting with representatives of health professional organizations. The meeting will be chaired by Sharon Smith Holston, Deputy Commissioner for External Affairs. The agenda will include presentations and discussions on the main topic of emerging infectious diseases. FDA staff will make presentations on FDA's involvement in the President's Food Safety Initiative, antimicrobial resistance, and issues in vaccine development and diagnostics. There will also be brief updates on

tobacco and the FDA Modernization Act.

DATES: The meeting will be held on Thursday, May 28, 1998, from 2 p.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Bethesda Holiday Inn, 8120 Wisconsin Ave., Bethesda, MD.

FOR FURTHER INFORMATION CONTACT: Peter H. Rheinstein, Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6630. *Registration:* There is no registration fee, however, space is limited. Persons will be registered in the order in which calls are received. Please call Betty Palsgrove at 301–827–6618 to register. Registrations also may be transmitted by FAX to 1–800–344–3332 or 301–443–2446. Please include the name and title of the person attending and the name of the organization.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide an opportunity for representatives of health professional organizations and other interested persons to be briefed by senior FDA staff. It will also provide an opportunity for informal discussion on these topics of particular interest to health professional organizations.

This public meeting is free of charge; however, space is limited. Registration for the meeting will be accepted in the order received and should be sent to the contact person. Registration should include the name and title of the person attending and the name of the organization being represented, if any.

Dated: May 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13410 Filed 5–15–98; 2:58 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

First Party Audit Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of industry exchange meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing an industry exchange meeting to discuss with the regulated industry a new initiative being considered by the agency. The First Party Audit Program (FPAP) is intended to gather information from selected human use pharmaceutical manufacturers regarding their quality assurance measures. This information would be submitted to FDA by those firms and would substitute, in some measure, for information the agency would otherwise obtain from its direct inspectional activities. The industry exchange meeting is intended to present the broad concepts of this initiative, discuss attendant issues, and obtain feedback from all interested parties as to the merits of proceeding with the project. This meeting is cosponsored by the Center for Drug Evaluation and Research's (CDER's) Office of Compliance and the Office of the Commissioner's Industry Small Business and Community Affairs Staff.

DATES: The industry exchange meeting will be held on June 23, 1998, from 9 a.m. to 4 p.m. Registration is required by June 12, 1998.

ADDRESSES: The industry exchange meeting will be held at the Hyatt Regency Bethesda Hotel, One Bethesda Metro Center, Bethesda, MD.

FOR FURTHER INFORMATION CONTACT: C. Russ Rutledge, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2455.

Those persons interested in attending this meeting should FAX or e-mail their registration to C. Russ Rutledge (FAX 301–594–2202 or e-mail via the Internet at ''rutledgec@cder.fda.gov''), including name of attendee(s), title, affiliation, mailing address, phone number, fax number, and e-mail address. There is no registration fee for this meeting, but advance registration is required. Interested parties are encouraged to register early because space is limited.

SUPPLEMENTARY INFORMATION: FDA relies in large part on information acquired during inspections of manufacturing facilities, conducted by the agency's investigators, to ensure that firms are meeting the minimum levels of product quality assurance for human drug products. Although the agency believes that full inspection by its investigators is the ideal situation, FDA is evaluating alternative methods of acquiring information it would otherwise directly obtain from traditional onsite inspections. One approach the agency is considering is the FPAP. The first party is the manufacturing firm itself. The concept is to limit program participation to those manufacturers FDA recognizes as having both a quality assurance program that is effective and a record of substantial compliance with FDA requirements. Program participation would be strictly voluntary. Firms the agency selects for the program would supply FDA with information from its self-audits apart from FDA onsite inspections. The agency would use this information along with modified inspections to document minimum levels of assurance of manufacturing quality of the pharmaceuticals produced in that site.

FDA is holding this industry exchange meeting to present the core concepts of FPAP, discuss the relevant issues, and afford interested parties the opportunity to pose questions and provide comments. The agency will consider this public input in deciding on whether and how to proceed with the program, initially on a pilot basis.

The agenda and any other relevant information will be available electronically via the Internet at ''http://www.fda.gov/cder/dmpq/fpap.htm'' beginning Monday, May 18, 1998.

Dated: May 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13163 Filed 5–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on June 23, 1998, 8 a.m. to 5 p.m., and on June 24, 1998, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, (For Federal Express Deliveries—Chapman Bldg., 801 Thompson Ave., rm. 200, Rockville, MD 20857) or FDA Advisory Committee Information Line,